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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,030	03/01/2004	Joel R. Studin	SDF 04-1	7162

7590

10/19/2005

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,030

Applicant(s)

STUDIN, JOEL R.

Examiner

Andrew M. Gilbert

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-13 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/24/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
2. The information disclosure statement (IDS) submitted on 6/24/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Breast Implant Injector and Method of Use.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 3, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiao (5201779). In reference to claim 1 Shiao discloses a disposable breast implant injector device comprising a hollow cylindrical barrel (10) with open and opposed filling and injection ends, an elongated plunger (30) capable of passing through the interior of the guide cylinder, and an injection tip of the barrel having elongated slots (11) extending from the injection end towards the filling end. In reference to claim 3 Shiao discloses an injection end having a narrower diameter than the opposed filling end (Fig 1a). In reference to claim 5 Shiao discloses an elongated plunger (30) with a flattened end (Fig 3 and 4) to provide sufficient area to apply force for pushing an implant through the barrel.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiao in view of Shippert (5507807). Shiao discloses the invention substantially as claimed in claim 1 except for the elongated slot extending from the injection end to the opposing filling end. Shippert teaches an applicator assembly for inserting substances into a body receiving area, such as a breast, with a opening in the side (32) of the assembly housing chamber, which can be of round cross-sectional shape (col 8, ln 3), that runs

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the length of the housing from the filling to the injection end (col 6, ln 51-55) and is opened or closed by a side panel (76) to assist in containing the substance to be dispensed within the housing chamber until the applicator is properly positioned to provide proper positioning of the substance within a body area. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention substantially as claimed by Shiao with a opening running the length of the cylindrical barrel from injection end to the opposed filling end for the purpose of providing an elongated opening extending from injection end to opposing filling end in order to assist in providing proper positioning of the breast implant within a body area.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiao in view of Kline (4341211). Shiao discloses the invention substantially as claimed in claim 1 except for the injection cylinder having an outward abutment surface adjacent to the filling end. Kline teaches an outward abutment adjacent to the filling end (3) to provide a gripping area (col 4, ln 54) on the injection cylinder to aide gripping of the injection device by the user. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the injection barrel (10) as taught by Shiao with an outward abutment surface adjacent to the filling end (3) as taught by Kline for the purpose of providing the injection barrel with a gripping area to aide gripping of the injection device by the user.

Allowable Subject Matter

9. Claims 6-13 are allowed.

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10. The following is a statement of reasons for the indication of allowable subject matter: No prior art of record could be found to teach or suggest the subject matter of the independent claim 6. The subject matter not found was the injector device having a hollow cylinder with an elongated slot extending from the injection end towards the filling end and an unfilled breast implant that fits within the hollow cylinder with a fill tube extending from the interior of the hollow cylinder through the elongated slot in combination with the other elements in the claim.

11. Claims 7-12 are allowable as being depending from independent claim 6.

12. No prior art of record could be found to teach or suggest the subject matter of independent claim 13. The subject matter not found was structure recited in the method comprising an injector device having a hollow cylinder with an elongated slot extending from the injection end towards the filling end and an unfilled breast implant that fits within the hollow cylinder with a fill tube extending from the interior of the hollow cylinder through the elongated slot in combination with the other elements, or steps, in the claim.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Becker (4643733) teaches a breast implant with a fill tube. Johnson et al (5258026) teaches a surgical method of implanting an unfilled breast implant with a fill tube wherein the fill tube extends from the end of the endoscope.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571)


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272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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